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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,064	10/11/2001	David J. O'Reilly	5050-0031	1787

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EXAMINER	
ZEMAN, MARY K	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,064	O'REILLY ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 6/9/04 have been fully considered but they are not completely persuasive. Any rejection not repeated below has been withdrawn.

Claims 1-22 are pending in this application. Claims 13-22 are newly added.

Newly submitted claims 17-22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. Claims 17-22 are drawn to a method of evaluating a test compound. The methods examined are for the manipulation and comparison of provided data. The newly added claims are for the evaluation of a compound, having differing steps, and differing desired goals. Examination of the newly added claims would require search in differing classifications and art areas than the previously pending claims. For example, the testing classes of 435/6 would need to be searched.

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, Claims 17-22 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP 821.03.

Rejections Maintained

Claims 1-9 remain rejected and new claims 13,14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. To the extent this rejection is newly applied it is necessitated by Applicant's amendments.

Applicant argues that the amended claims do recite statutory subject matter, and that the step of "predicting a biological activity" provides a concrete, tangible and useful result. These arguments are not persuasive. Claim 1 merely rearranges previously provided data. Each of the expression profiles, bioassay profiles and compound information are previously provided. The "correlation information" appears to be previously provided. The method merely selects and compares the data. The final "predicting an activity" is not a concrete tangible and useful result as there is no indication of how to perform the step, what type of result is obtained, what the thresholds are for a positive or negative result, etc. Dependent claims 2-6 do not further limit the method steps or generate a concrete tangible and useful result. These claims further describe the previously provided data. New claim 13, which adds a display step to the method of claim 1,

does not make the result of the method concrete tangible and useful. Merely displaying a piece of data does not make it statutory. Claim 7 is nearly identical to claim 1, wherein previously provided data is selected and correlation information is used for comparison. The predicting step of claim 7 does not provide a concrete tangible and useful result. Claims 8 and 9 describe the previously provided data. These limitations do not modify the steps of the method, and do not provide a concrete tangible and useful result. New claim 14, which adds a display step to the method of claim 7, does not make the result of the method concrete tangible and useful. Merely displaying a piece of data does not make it statutory.

As set forth previously, MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See Alappat, 33 F.3d at 1543, 31USPQ2d at 1556-57 (quoting Diamond v. Diehr, 450 U.S. at 192, 209 USPQ at 10). See also Alappat 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing O 'Reilly v. Morse, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in State Street, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in Alappat, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc)."

Claims 1-3, 5-8, and 10-16 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bassett Jr et al. (US 6,453,241 B1) for the reasons set forth in the previous office action. To the extent this rejection is newly applied, it is necessitated by Applicant's amendments.

Applicant argues that Basset Jr. does not provide a database which comprises all the information: gene expression profiles, bioassay profiles and compound information. This argument is not persuasive. Basset Jr. provides gene expression information for a variety of cell types. This data includes: qualitative signal intensity levels, expression ratios, p-values, conditions of the experiment, etc.) The data can be gathered from a variety of sources including: SAGE, Northern or Southern blots, antibody studies, chemiluminescence studies, Lynx, READS

and drug screening methods. Gene expression "fingerprints" can be provided. Also provided is gene expression information for cells under various conditions, such as the application of a drug or compound (a perturbation). Information about the drug (structure, dosage, etc) and its effects (biological activity) are provided (meeting the limitations of claims 13-16 for display of product information that is related to testing). Correlation information across sets of expression array experiments is also provided as pre-computed data. Comparisons of the sets of data by similarity matricies, clustering or hierarchies allow for identification of similar activities for unknown compounds. (ROAST and FINISH algorithms of Basset Jr.) Basset Jr. discusses the results of the comparisons at column 17: "Given one or more known successful drugs of drug target deletion profiles, this technique allows the identification of similar profiles that represent new prospective drugs or drug targets affecting or involved in the same cellular pathway or process." This meets the "predicting" step of the rejected claims. The comparisons can be viewed in multiple formats depending on the nature of the selected information. The methods of Basset Jr. are all computer implemented, and these programmed computers meet the limitations of the system claims. It is noted that the claimed systems do not actually have to predict an activity, merely contain the means which would be useful therein. These limitations are intended use limitations which do not limit the structure of the system or software.

New Grounds of Rejection

Claim rejections- 35 USC 112

The following is a quotation of the second paragraph of 35 USC 112:

> The specification shall conclude with one or more claims specifically pointing out and distinctly claiming the subject matter which applicant regards as his invention.

Claims 1-16 are rejected under 35 USC 112, second paragraph as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as his invention. To the extent this rejection is newly applied it is necessitated by Applicant's amendments.

In claim 1, the phrase "chemical genomic data" is unclear. Genomic data is data about the DNA present in a cell or individual, and is not synonymous with chemical data about a product.

Chemical is not a general modified of genomic. It would appear this phrase may be intended to read "chemical and genomic data. Claims 7, 10 and 12 have a similar problem.

Further in claim 1, step c) is indefinite as the step lacks positive active steps by which the "using" and "predicting" are to be carried out. It is unclear what specific data manipulations are to be performed in the execution of the method. Claims 7, 10 and 12 have similar problems.

Claims 3, 4, and 13 lack antecedent basis in claim 1. Claim 1 has been amended to remove "product information" and no references remain to any product. Therefore, claims limiting the product information lack basis.

Claims 8, 9 and 14 lack antecedent basis in claim 7. Claim 7 has been amended to remove "product information" and no references remain to any product. Therefore, claims limiting the product information lack basis.

Claim 15 lacks antecedent basis in claim 10, and claim 16 lacks antecedent basis in claim 12. Claims 10 and 12 have been amended to remove "product information" and no references remain to any product. Therefore, claims limiting the product information lack basis.

Claims 10 and 12 each have been amended to recite "means plus function" language that is not clearly correlated in the specification with a specific structure or hardware that performs the function. In claim 10, the "means for identifying and selecting correlation information... that is useful to predict a biological activity..." is the unclear "means plus function" limitation. The specification does not appear comprise an express, implied or inherent disclosure of hardware or software or a combination of hardware and software that performs the function. The same "means plus function" limitation is present in claim 12.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Basset Jr in view of Pati. To the extent this rejection is newly applied, it is necessitated by Applicant's amendments.

Claims 4 and 9 set forth that the display of product information includes a hyperlink for purchasing said product.

As set forth above, Bassett Jr et al. (US 6,453,241 B1) disclose systems and methods for analyzing chemical and biological signal data wherein data is selected from previously provided data, the selected data is compared and correlated to predict an activity. Basset Jr. provides gene expression information for a variety of cell types. This data includes: qualitative signal intensity levels, expression ratios, p-values, conditions of the experiment, etc.) The data can be gathered from a variety of sources including: SAGE, Northern or Southern blots, antibody studies, chemiluminescence studies, Lynx, READS and drug screening methods. Gene expression "fingerprints" can be provided. Also provided is gene expression information for cells under various conditions, such as the application of a drug or compound (a perturbation). Information about the drug (structure, dosage, etc) and its effects (biological activity) are provided (meeting the limitations of claims 13-16 for display of product information that is related to testing). Correlation information across sets of expression array experiments is also provided as pre-computed data. Comparisons of the sets of data by similarity matricies, clustering or hierarchies allow for identification of similar activities for unknown compounds. (ROAST and FINISH algorithms of Basset Jr.) Basset Jr. discusses the results of the comparisons at column 17: "Given one or more known successful drugs of drug target deletion profiles, this technique allows the identification of similar profiles that represent new prospective drugs or drug targets affecting or involved in the same cellular pathway or process." This meets the "predicting" step of the rejected claims. The comparisons can be viewed in multiple formats depending on the nature of the selected information. The methods of Basset Jr. are all computer implemented, and these

programmed computers meet the limitations of the system claims. It is noted that the claimed systems do not actually have to predict an activity, merely contain the means which would be useful therein. These limitations are intended use limitations which do not limit the structure of the system or software.

Basset Jr. does not specifically disclose the display of hyperlinks for facilitating the purchase of a particular product.

Pati et al. (US 2002/0032530) disclose integrated genomics systems which can be used in the analysis of chemical and genomic data. It provides a database comprising information, input means, selection means, correlation means, and display means. Means for purchasing products are also included. (see also paragraphs 0017-0030). The database can comprise information as to how gene expression is affected by treatment with a particular drug (gene expression signature), as well as information about that drug (drug signature) (see paragraph 0031, 0034). Then data is displayed that is relevant to the gene, expression profile, or high throughput screening. The displayed information is correlated to the originally displayed expression signature or drug signature (paragraphs 0036-0038). Related available product information is displayed, and can be directly purchased by the user through the use of a hyperlink.

It would have been obvious to one of ordinary skill in the art at the time the inventionwas made to have modified the display of information of Basset Jr to include hyperlinks for the direct purchase of various products as set forth by Pati. One would have been motivated to add the hyperlink so that users of the methods and systems would have easy access to relevant products identified by the data analysis methods. The product would have been easy to order for use in further testing and validating the predicted activity. The methods and systems of Basset Jr and Pati comprise the same types of information such that one would have had a reasonable expectation of success at implementing a hyperlink to direct purchase information. Therefore, the invention would have been prima facie obvious to one of skill in the art at the time the invention was made absent evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MARY K. ZEMAN
PRIMARY EXAMINER

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